

REMARKS

The Office Action mailed March 13, 2001 (hereinafter the Office Action), has been received and reviewed. Claims 1 through 9 and 13 through 21 are currently pending in the application. However, claims 1 through 9 and 13 through 21 stand rejected. Applicants have herein canceled claims 16 through 21 without prejudice or disclaimer, and Applicants respectfully request reconsideration of the application in light of the remarks set forth herein.

35 U.S.C. § 112 Rejections

Claims 16 through 21 are rejected in the Office Action under 35 U.S.C. § 112, second paragraph. However, claims 16 through 21 are cancelled herein without prejudice or disclaimer. Applicants respectfully submit, therefore, that the rejection asserted under 35 U.S.C. § 112, second paragraph is no longer applicable and respectfully request that such rejection be withdrawn.

35 U.S.C. § 103(a) Obviousness Rejections

Each of pending claims 1 through 9 and 13 through 21 stands rejected under 35 U.S.C. § 103(a) ("Section 103") as being unpatentable over Magruder et al. (U.S. Patent No. 5,630,808) or over Magruder et al. taken in combination with Theeuwes et al. (U.S. Patent No. 4,088,864). A rejection under Section 103(a), however, is improper and will be overturned unless a *prima facie* case of obviousness is established against the rejected claims. *In re Rijckaert*, 9 F.3d 1531,

1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). Applicants respectfully submit that the teachings of the references cited in the Office Action, whether taken alone or in combination, fail to provide evidence sufficient to properly establish the *prima facie* obviousness of any of the pending claims. Thus, Applicants respectfully request that the rejections of claims 1 through 9 and 13 through 21 under Section 103 be withdrawn.

As is set forth in M.P.E.P. 706.02(j), a *prima facie* case of obviousness under Section 103 can not be established unless three criteria are met:

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The examiner bears the burden of establishing these three criteria based on the prior art, and, significantly, this burden can be met "only by showing some **objective teaching** in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references." *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (emphasis added).

Claims 1 through 9, 13, and 15 through 21 are rejected in the Office Action as being unpatentable over Magruder et al. Because claims 16 through 21 are cancelled herein without prejudice or disclaimer, however, Applicants respectfully submit that the rejection of these claims under Section 103 in light of Magruder et al. is no longer relevant and respectfully request

that such rejection be withdrawn. Applicants address the rejection of claims 1 through 9, 13, and 15 through 21 under Section 103 only to the extent that such rejection applies to claims 1 through 9, 13, and 15.

Applicants respectfully submit that the teachings of Magruder et al. fail to establish the *prima facie* obviousness of any of claims 1 through 9, 13, and 15. In particular the teachings of Magruder et al. fail to teach or suggest each of the limitations included in claims 1 through 9, 13, and 15. Claim 1 is an independent claim that recites a dosage form comprising "an outer wall defining an interior compartment," "at least one laser formed orifice in the outer wall," and "a barrier layer disposed between the outer wall and the interior compartment . . . wherein the barrier layer comprises a material that allows the barrier layer to remain intact during formation of the at least one laser formed exit orifice." Claims 2 through 9, 13 and 15 depend either directly or indirectly from claim 1, and therefore incorporate each of the limitations included in claim 1. In contrast to the subject matter recited in these claims, however, the delivery system taught in Magruder et al. does not include an outer wall defining an interior compartment with a barrier layer disposed between the outer wall and the interior compartment. Moreover, the teachings of Magruder et al. fail to suggest a dosage form having such a configuration, much less a dosage form wherein the barrier layer comprises a material that allows the barrier layer to remain intact as the at least one laser formed exit orifice is formed in the outer wall. Therefore, Magruder et al. fails to teach or suggest each of the limitations included in any of claims 1 through 9, 13, and 15, and Applicants respectfully request that the rejection of these claims under Section 103 as being unpatentable over Magruder et al. be withdrawn.

Claims 1 through 9 and 13 through 21 are rejected in the Office Action as being unpatentable over Magruder et al. further in view of Theeuwes et al. However, because claims 16 through 21 are cancelled herein without prejudice or disclaimer, Applicants respectfully submit that the rejection of these claims under Section 103 in light of Magruder et al. and Theeuwes et al. is no longer relevant and respectfully request that such rejection be withdrawn. Applicants address the rejection of claims 1 through 9 and 13 through 21 under Section 103 only to the extent that such rejection applies to claims 1 through 9 and 13 through 15.

Applicants respectfully submit that the teachings of Magruder et al. fail to establish the *prima facie* obviousness of any of claims 1 through 9 and 13 through 15. In particular the combined teachings of Magruder et al. and Theeuwes et al. fail to teach or suggest each of the limitations included in claims 1 through 9, 13, and 15. Claim 1 is an independent claim that recites a dosage form comprising "an outer wall defining an interior compartment," "at least one laser formed orifice in the outer wall," and "a barrier layer disposed between the outer wall and the interior compartment . . . wherein the barrier layer comprises a material that allows the barrier layer to remain intact during formation of the at least one laser formed exit orifice." Claims 2 through 9 and 13 through 15 depend either directly or indirectly from claim 1, and therefore incorporate each of the limitations included in claim 1. Though Theeuwes et al. may teach a method for making passageways in pills using lasers, the combined teachings of Magruder et al. and Theeuwes et al. fail to teach or suggest a dosage form having an outer wall defining an interior compartment with a barrier layer disposed between the outer wall and the interior compartment. The combined teachings of Magruder et al. and Theeuwes et al. also fail

to teach or suggest a dosage form including a barrier layer disposed between an outer wall and an interior compartment defined by the outer wall, wherein the barrier layer comprises a material that allows the barrier layer to remain intact as the at least one laser formed exit orifice is formed in the outer wall. Therefore, the combined teachings of Magruder et al. and Theeuwes et al. fail to teach or suggest each of the limitations included in any of claims 1 through 9 and 13 through and 15, and Applicants respectfully request that the rejection of these claims under Section 103 as being unpatentable over the combination of Magruder et al. and Theeuwes et al. be withdrawn.

CONCLUSION

Claims 1 through 9 and 13 through 15 are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Examiner determine that additional issues remain which might be resolved by a telephone conference, he is respectfully invited to contact Applicants' undersigned attorney.

Respectfully Submitted,



Samuel E. Webb

Registration No.: 44,394

ALZA Corporation

Intellectual Property Department, M10-3

P.O. Box 7210

Mountain View, CA 94039

(650) 564-5106

SEW/eg

Date: May 30, 2002